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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,036	02/18/2004	Robert Belly	VDX-5001 USNP	3966
27777	7590	05/10/2006		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER
			1723	
DATE MAILED: 05/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,036

Applicant(s)

BELLY ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0204</u> . | 6) <input type="checkbox"/> Other: ____. |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Spelsberg patent 4,307,846. Spelsberg discloses a device having a disruption element (pestle 38) for disrupting cells or tissues in conjunction with a sample container 12 (column 4, lines 12-14), in which the disruption element has a slightly smaller dimension than the inside dimension of the container (column 4, lines 19-27).

For claims 2 and 3, given the disclosed clearance of Spelsberg of a matter of 0.0005-0.002 inches (column 4, lines 19-27), the element is much greater than .75 times the diameter of the container.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spelsberg in view of Depperman patent 6,880,771. Claims 4-6 differ from Spelsberg in requiring the disruption element to comprise a dense material, or specifically a stainless steel ball. Depperman teach a disruption element of a stainless steel ball or other dense material inside a container for disrupting tissue or cells (Abstract, column 1, lines 12-15, column 2, lines 27-30 and column 7, lines 43-54). It would have been obvious to one of ordinary skill in the art to have manufactured the disruption element of Spelberg of stainless steel and made it ball-shaped, since the dense material would effect a more rapid and complete disruption and homogenization of the tissue, without loss.

Claims 7-13,16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spelsberg in view of Gautsch et al patent 6,235,501. Spelsberg discloses disrupting tissues or cells with a disruption element placed into a container (Abstract, column 1, lines 12-25, colujmn 2, lines 35-50, etc.).

The method claims firstly differ in requiring the disruption element for 45 seconds or less, although Spelsberg discloses that the disruption can proceed rapidly (column 1, lines 64-68). Gautsch teach that disruption elements can effect disruption of cell tissues in a manner of seconds (column 13, line 64-column 14. It would have been obvious to one of ordinary skill in the art to have operated the disruption element on discrete sample volumes for periods of 45 seconds or less as taught by Gautsch, so as to enable the processing of a greater total volume/quantity of cell tissue over time.

Spelsberg also discloses the cell or tissue being disrupted is contacted in the container in a stabilizing solution (column 2, lines 35-40). The claims also differ in requiring that a "nucleic acid stabilizing" solution be added to the container. Gautsch also teaches adding a solution to stabilize and homogenize any type of cell tissue being disrupted and teach that extraction of nucleic acids such as DNA or RNA, may be extracted (Abstract, column 16, line 42-column 17, line 5). It would have been obvious to one of ordinary skill in the art to have specifically added a "nucleic acid" solution to the material being disrupted in the Spelsberg method , as taught by Gautsch, to enable later separation of desired nucleic acid material from the remainder of the cell tissue, since study and isolation of DNA or other nucleic acid constituents is valuable in the research and development of many medical and pharmaceutical products.

For claims 8 and 17, Gautsch teach that any of diverse cells or tissues may be disrupted including lymph cell tissue at column 16, lines 8-11.

For claims 10-12, Spelsberg again discloses a very small clearance between disruption element and container (column 4, lines 19-27).

For claim 13, Spelsberg discloses the disruption element being of Teflon (column 6, line 43), which is a denser material than some other materials.

For claim 16, Spelsberg discloses "continuous", hence "intra-operative" operation (column 2, lines 38-39 and column 1, lines 53-65) of the device and method.

Regarding claim 9 and claims dependent therefrom, Spelsberg also discloses that constituents of cell tissue are eventually separated from the solution containing the cell tissue being disrupted (column 1, lines 12-24, column 5, lines 1-3). Independent claim 9, and claims dependent therefrom, further differ in requiring that nucleic acids be extracted from the solution of cell or tissue. Gautsch teach such extraction of DNA, hence nucleic acids, at (Abstract, column 13, lines 2-3, etc.). It would have also been obvious to have effected such separation or extraction of Gautsch in employ of a method utilizing the Spelsberg apparatus, to enable later separation of desired nucleic acid material from the remainder of the cell tissue, since study and isolation of DNA or other nucleic acid constituents is valuable in the research and development of many medical and pharmaceutical products.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spelsberg in view of Gautsch et al as applied to claims 7-13 above, and further in view of Depperman. Claims 14-16 differ from Spelsberg in requiring the disruption element to comprise a dense material, or specifically a stainless steel ball. Depperman teach a disruption element of a stainless steel ball or other dense material inside a container for disrupting tissue or cells (Abstract, column 1, lines 12-15, column 2, lines 27-30 and column 7, lines 43-54). It would have been obvious to one of ordinary skill in

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the art to have manufactured the disruption element of Spelsberg of stainless steel and made it ball-shaped, since the dense material would effect a more rapid and complete disruption and homogenization of the tissue, without loss.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Murphy patent 5,374,522 is of interest with regard to release of either RNA or DNA from cell tissue by mechanical disruption; Destafano et al patent 5,829,696 is of interest with respect to a cell disruptor having a small clearance between the container and disruptor, in a device where the container is sealed, rather than allowing flow therethrough.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

May 6, 2006


JOSEPH DRODGE
PRIMARY EXAMINER